

REMARKS

Record is made of an interview with the Examiner on July 23, 2008 in which the Examiner was requested to clarify the status of the rejected and allowed claims in the office action mailed June 24, 2008. The Examiner is thanked for the courtesies extended by the Examiner to the undersigned at the interview and the provision of a second office action mailed August 25, 2008 setting forth the status of the claims, i.e., allowed and rejected. It is noted in this regard that the Examiner states that claims 12, 16 and 18-22 are pending, claims 12, 16 and 18-22 are allowed, and claims 33 and 34 are rejected. It is pointed out that it was inadvertently omitted to include claims 33 and 34 as pending in this application.

Claims 12, 16, 18-22 and 33-34 are present in the application. Of these claims, claims 12, 16, and 18-22 have been allowed.

Claims 33 and 34 were added with the amendment filed with the RCE on May 21, 2008, and stand rejected as unpatentable over Griesbach (US 2004/0123939) in view of Morman (US 2004/0091752) under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of this rejection.

Independent claims 12 and 21, which have been allowed, define the cast film as being formed of:

- at least two outer layers consisting of a polypropylene (PP) resin selected from the group consisting of PP homopolymers and PP copolymers; and
- at least one barrier layer consisting of low density polyethylene (LDPE) or a blend of LDPE and linear low density polyethylene (LLDPE).

In independent claim 33, the cast film layer is defined as comprising:

- at least two outer layers consisting of PP or blends of polypropylene (PP) and polyethylene (PE); and
- at least one barrier layer consisting of linear low density polyethylene (LLDPE).

In independent claim 34, the cast film layer comprises:

- at least two outer layers consisting of polypropylene (PP) or blends of polypropylene (PP) and polyethylene (PE); and
- at least one barrier layer consisting of a blend of 30% linear low density polyethylene (LLDPE) and 70% low density polyethylene (LDPE).

Examples 1 and 3 in the specification (pages 9-11 and 12-14) respectively disclose cast film layers as follows:

Example 1 (ABA)

Outer layers (A) blend of polypropylene (PP) and polyethylene (PE)

Core layer (B) LDPE

Example 3 (ABA)

Outer layers (A) polypropylene (PP)

Core layer (B) blend of linear low density polyethylene (LLDPE) and low density polyethylene (LDPE).

Applicant submitted in their application and again in a Rule 132 Declaration data utilizing extruded films (ABA) the subject matter of Examples 1 and 3 of the application

and an extruded film (AAA), corresponding to Example 2 of the application (A=PE) in order to compare wet/dry peel strengths and barrier strengths, particularly on aging and after EtO sterilization.

The data, as set forth in the specification clearly establish the criticality of the structure recited in Applicant's claims including claims 33 and 34. Example 1 corresponds to the recitation ABA in claim 33 and Example 3 to the recitation ABA in claim 34.

The tabulated and graphically presented data which follows is derived from the specification and has also been presented in declaration form. The origin of the data can be seen from the following table which is a composite duplicate of data presented in Tables 1 and 2 of the specification. It is noted that the EtO sterilization data was obtained 18-19 days following production of the laminates.

| | | Example 1 | | | Example 2 | | | Example 3 | | |
|-------------------------------|-----------|-----------------------|-------------------------------|-------------------------|-----------------------|-------------------------------|-------------------------|-----------------------|-------------------------------|-------------------------|
| Date of Testing | Units | At time of production | After Aging (approx. 1 month) | After EtO Sterilization | At time of production | After Aging (approx. 1 month) | After EtO Sterilization | At time of production | After Aging (approx. 1 month) | After EtO Sterilization |
| Spunbond Weight (outer layer) | gsm | | 30 | | | 30 | | | 30 | |
| Spunbond Weight (inner layer) | gsm | | 20 | | | 20 | | | 20 | |
| Film Weight | gsm | | 18 | | | 18 | | | 18 | |
| Adhesive add-on (outer layer) | gsm | | 3 | | | 3 | | | 3 | |
| Adhesive add-on (inner layer) | gsm | | 2 | | | 2 | | | 2 | |
| Handelometer, MD | grams | | 89 | | | 86 | | | 87 | |
| Handelometer, CD | grams | | 41 | | | 47 | | | 44 | |
| Dry inner Peel Strength (CD) | g/in | 81 | 137 | 157 | 74 | 138 | 108 | 83 | 178 | 260 |
| Wet Inner Peel Strength (CD) | g/in | 97 | 193 | 179 | 90 | 37 | 34 | 117 | 267 | 375 |
| Blood barrier (ASTM F1670) | Pass/fail | pass | Pass | Pass | Pass | Pass | pass | Pass | Pass | pass |

The unexpected results are significant as is clear from the following summary:

| | Wet Peel Strength (g/in) | | |
|-----------|--------------------------|---------------|-------------------------|
| | As made | After 1 month | After EtO sterilization |
| Example 1 | 97 | 193 | 179 |
| Example 2 | 90 | 37 | 34 |
| Example 3 | 117 | 267 | 375 |

This data was obtained by comparing two composite laminates as claimed (examples 1 and 3) with a laminate of AAA structure (example 2). The composite structure of the film layer in each example was:

| <u>Example 1 (ABA)</u> | <u>Example 2 (AAA)</u> | <u>Example 3 (ABA)</u> |
|------------------------|------------------------|------------------------|
| PP/PE Blend | LDPE | PP |
| LDPE | LDPE | LDPE/LLDPE blend |
| PP/PE blend | LDPE | PP |

The unexpected results set forth in the specification and Declaration clearly support applicant's position that the invention is not obvious and would not have been foreseen by one skilled in the art.

Evidence of unexpected properties must be considered in determining the nonobviousness of a claimed invention.

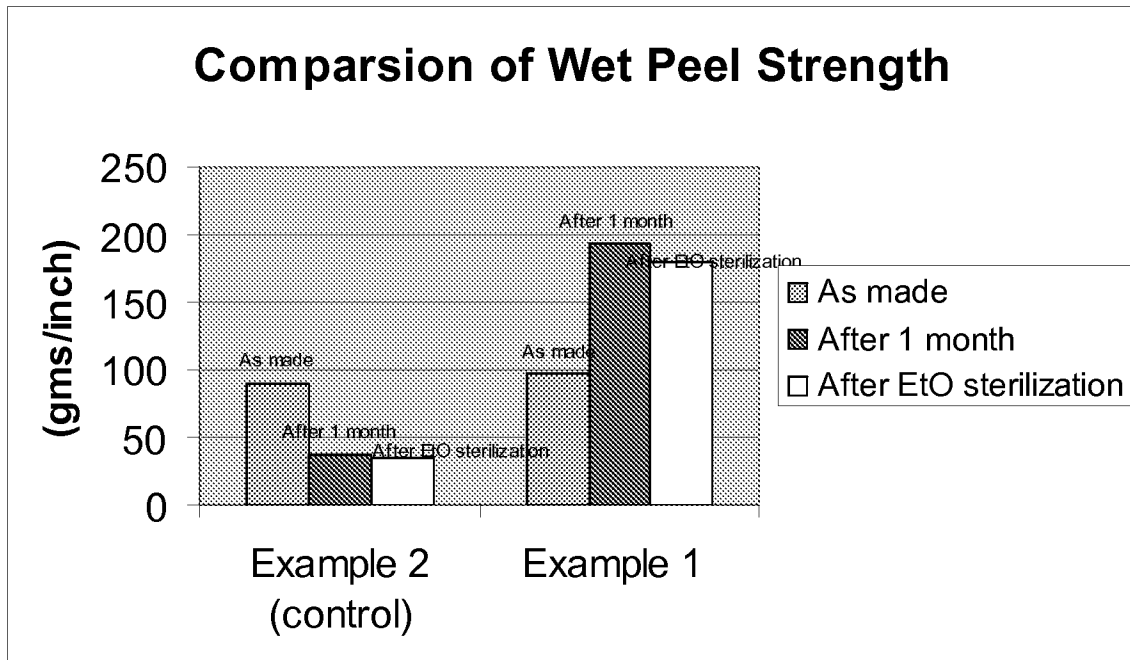
As to the rejection as applied, the Examiner relied on Griesbach as teaching "a multi-layer film comprising a core layer comprising blends of polypropylenes and two skin layers comprising blends of polyolefins, ethylene acrylic acid...positioning the multi-layer film between two outer non-woven layers."

The Examiner's position was that the invention of claims 33 and 34 is obvious over Griesbach in view of Morman. The combination of Griesbach in view of Morman does not make obvious the composite laminate described and claimed in this application because the combination proposed by the Examiner fails to teach or suggest the applicant's adhesively bonded laminate, its improved barrier properties and high wet peel strength associated with its composition and structure.

The Examiner admits that "Griesbach et al. fails to teach a barrier layer comprising low density polyethylene" and relies on Morman to cure this omission, i.e., Morman is relied on as teaching "a film comprising either linear low density polyethylene or low density polyethylene... in a laminate structure where liquid

impermeable properties are desired.” It appears to the Examiner that the polyolefins employed by Greisbach et al., are functionally equivalent to the low density polyethylene polymers of Morman for the desired use of forming an impermeable film, “absent unexpected results.”

There are unexpected results in this case. First, the Examiner is asked to consider the chart below prepared from the data presented in table 1 of the original specification of this application comparing the wet peel strength properties of composite laminates of example 1 and example2.

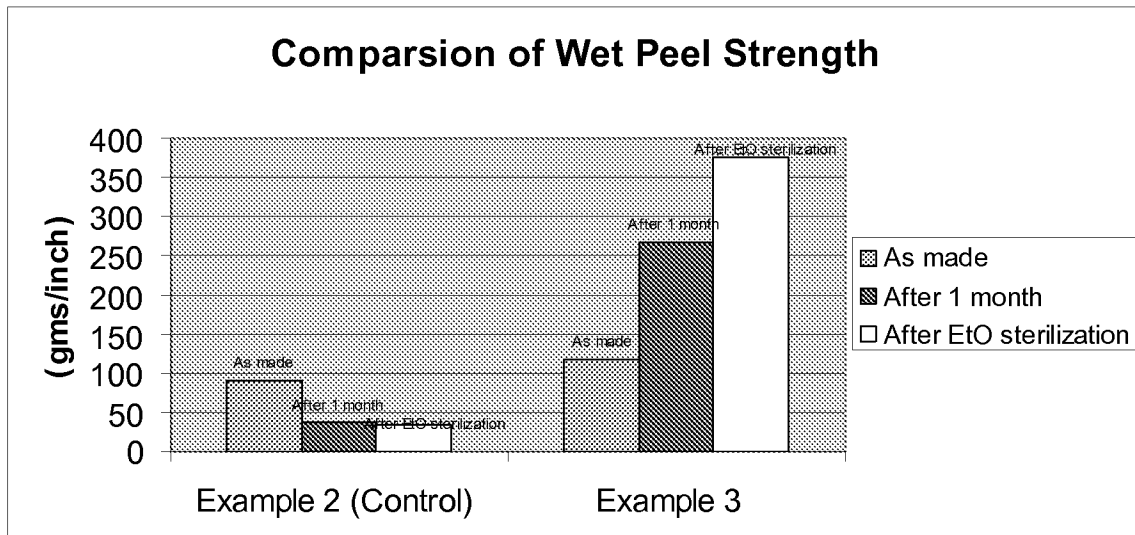


The only difference between the two products tested is that in example 1 the sheath layers are a blend of PE and PP, while in example 2 it is LDPE.

As is clear from the chart, the difference in wet peel strength after 1 month from the making of these products and after EtO sterilization, was about several multiples of

the original value. This is significant, and not to have been foreseen from Griesbach alone or Griesbach in view of Morman.

Second, consider the chart below derived from the data presented in tables 1 and 2 of the original specification and which are directed to the wet peel strength data for Examples 2 and 3 after 1 month and after EtO sterilization. The laminate of Example 3 in addition to having PP as the polymer component in both of the sheath layers has a core layer of an LDPE/LLDPE blend while in Example 2, all of the layers are LDPE.



As is clear from the chart, the difference in wet inner peel strengths in each instance is significant. This is in considerable part due to the nature of the core layer, noting that for purposes of the invention LDPE and LDPE/LLDPE are equivalents (members of a Markush group) and in the core layer's combination in the case of Example 3 with the outer polypropylene layers. The increase is almost four-fold for wet peel strength for the laminate of Example 3 while the wet peel strength decreased both after 1 month and EtO sterilization for the laminate of Example 2.

As to the Examiner's conclusion that it would be obvious to one skilled in the art to substitute the low density polymers of Morman for the barrier layer proposed by Griesbach, this is not true at least for the unpredictability of the advantage to doing so.

Morman's laminate is an entirely different construct, and more particularly a breathable, substantially liquid impermeable film and laminate. The term "breathable" is defined as having a defined water vapor transmission, i.e., "breathable materials typically rely on molecular diffusion of vapor, or vapor passage through micropores..." (Morman, paragraph 19). The Morman material is microporous. Such micropores would interfere with obtaining the sought after properties of the claimed laminate, i.e., viral barrier properties.

Further, the Morman disclosure of suitable polymers is a shot gun disclosure, and any of the polymers having the required extendable property would be suitable for use in Morman, albeit not in the instant invention. The only suggestion to use a particular polymer would come from the Applicant's disclosure which is clearly not available for that purpose.

Finally, Applicants have submitted data establishing unexpected results of the claimed constituents of the film. The Examiner's combination of references does not recognize the significance of Applicant's choice of specific polymers in the core and skin layers of the film, film, which is basic to Applicant's invention.

As to the adhesive lamination and positioning the multiplayer film between two outer nonwoven layers limitations, it is noted that in Griesbach (0012), the former is an alternative to thermal bonding with surfactant treatment. This is not the case in applicant's invention. Furthermore in either case as noted above, there is no teaching or

suggestion of using LDPE/LLDPE blend as the barrier layer or combining it with outer polypropylene layers (Example 3, claim 34) or LDPE as barrier layer in combination with outer PP/PE blend outer layers (Example 1, claim 33). This has been disclosed by applicant and reinforced in the submitted declaration.

In view of the above, it is submitted that claims 33 and 34 are allowable to the applicant.

Therefore, Applicant submits that claims 12, 16, 18-22, 33 and 34 are allowable, and notification to that effect is respectfully requested.

Respectfully Submitted,

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